



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,561	12/08/2003	Sharad K. Govil	MTI 3.0-025 DIV DIV	4254
530 7590 12/11/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WEBMAN, EDWARD J	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,561	<b>Applicant(s)</b> GOVIL ET AL.	
	<b>Examiner</b> Edward J. Webman	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-67, 69-76, 78-111 and 113-119 is/are pending in the application.
- 4a) Of the above claim(s) 29-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67, 69-76, 78-111, 113-119 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67, 70-76, 79-88, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (US 5,474,783).

Miranda et al teach a transdermal comprising a drug, an acrylate polymer and a polysiloxane (abstract). 2-96% polyacrylate and 98-4% polysiloxane is disclosed (column 4 lines 10-12). The acrylate polymer is composed of at least 50% alkyl acrylate monomer (column 9 lines 38-40). Butyl acrylate is disclosed (column 9 line 44). The drug is 0.3-50% of the composition (column 8 line 67-column 9 line 2). Selegiline (a liquid) is disclosed (column 12 line 29). Ethanol (bp 78.5° C=168° F) is disclosed (column 15 line 14).

It would have been obvious to one of ordinary skill to make a composition comprising an acrylate to deliver selegiline to achieve the beneficial effect of transdermal delivery in view of Miranda et al. As to the claimed hydrophobic acrylic polymer, Miranda et al teach at least 50% butyl acrylate as cited above, which renders the polymer hydrophilic. It would have further been obvious to one of ordinary skill to select ethanol to achieve a dry composition because it is volatile.

Applicants argue that Miranda et al provide no motivation to select ethanol, however, motivation for one of ordinary skill is provided. The examiner notes that, for independent claims 67 and 85 "substantially free of low volatility solvents" can include as much as 49% of such solvents. Applicants do not define "substantially free".

Claims 67, 70-76, 79-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al (US 5,462,746).

Wolter et al teach a transdermal comprising an adhesive, a drug or salt thereof, and, when the salt is present, an element containing basic groups (abstract). Deprenyl (selegeline) is disclosed (column 3 line 44). Ethyl acetate (bp 77° C=172° F) is specified (column 4 line 64). DURO-TAK 2516 [disclosed in applicants' specification in Table III as an acrylate polymer comprising ethylhexyl acrylate and methyl acrylate, crosslinked with aluminum] is specified (column 5 line 9).

It would have been obvious to one of ordinary skill to make a composition comprising deprenyl and an acrylate polymer to achieve the beneficial effect of transdermal delivery in view of Wolter et al. It would have further been obvious to one of ordinary skill to select ethanol to achieve a dry composition because it is volatile. As to the claimed percent ranges of of acrylate polymer, non-aqueous solvent and drug, Wolter et al teach suitable amounts. Absent a showing of criticality, optimum suitable amounts may be obtained by routine experimentation.

The response to applicants' arguments regarding Miranda et al are incorporated herein as applied to Wolter et al. Additionally, applicants argue that element b) in Wolter et al contains low volatile solvents. However, such solvents are optional.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g.,

In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67, 69-76, 78-111, 113-119 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 1-17 of U.S. Patent No. 7,070,808 and 7,150,881 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '881 claims encompass the instant claims regarding the presence of solvents and additional actives and the '808 claims encompass the instant claims regarding the scope of the alkyl acrylates and crosslinking. As to the claimed secondary adhesives adhesives, the addition of such would be an obvious expedient in the transdermal compositions of '881 and '808.

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

Application/Control Number:  
10/730,561  
Art Unit: 1616

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor J. Richter, can be reached on 571-272-06246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500